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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/776,989 | 02/11/2004 | Scott Saunders | 101353-232 | 5871 |

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| EXAMINER |
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LUCAS, ZACHARIAH

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| ART UNIT | PAPER NUMBER |
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1648

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/776,989 | Applicant(s) SAUNDERS ET AL. | |
| | Examiner Zachariah Lucas | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 5-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-16 are pending in the application. In the prior action, mailed on May 11, 2005, claims 1-16 were pending, with claims 1-4, 15, and 16 under consideration and rejected; and claims 5-14 withdrawn from consideration. In the Response filed on November 14, 2005, the Applicant amended claims 1, 2, 4, and 15.
2. Claims 1-4, 15, and 16 are pending and under consideration.
3. Because this action raises new grounds of rejection, it is made Non-Final.

Specification

4. **(Prior Objection- Withdrawn)** The disclosure was objected to because of the following informalities: On pages 50 of the application, the specification referred to “transforming growth factor- χ (TGF- β).” In view of the amendment of the application, the objection is withdrawn.

(Prior Objection- Withdrawn) The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). The specification did not provide antecedent basis support in the written description (other than the originally filed claims) for polypeptides comprising amino acids SEQ ID NO: 20-41 of SEQ ID NO: 9. In view of the amendment of pages 48-50 of application, the objection is withdrawn.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **(Prior Rejection- Maintained in part)** Claims 1-4, 15, and 16 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention to the full extent of the claims. The rejection is withdrawn from claim 16.

The claims were rejected because, the specification, while being enabling for fusion polypeptides comprising the residues 20-41 of SEQ ID NO: 9, and for fragments thereof that comprise the Xac-Z-Ser-Gly-Ser-Gly heparan sulfate (HS) binding sequence, the claims were not enabled for any peptide of residues 20-41 of SEQ ID NO: 9 with any number of conservative substitutions therein. This is especially true for substitutions in the SGSG sequence. The claims have been amended to require the presence of the Ser-Gly-Ser-Gly sequence. However, it is noted that the application specifically indicates on page 4 of the application that the Xac-Z-Ser-Gly-Ser-Gly formula represents the required heparin sulfate binding sequence. As the amended claims do not require the presence of this complete formula, and as this formula is indicated a required for the claimed function, the rejection is maintained on this basis.

7. **(Prior Rejection- Maintained in part)** Claims 1-4, 15, and 16 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement with respect to the genus of inventions comprising any variant of SEQ ID NO: 9, or variants of down

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to 50% identity thereto, which maintain the ability of SEQ ID NO: 9 to bind to heparan sulfate.

The rejection is withdrawn from claim 16.

As indicated above, the claims have been amended to require the presence of the Ser-Gly-Ser-Gly sequence. However, it is noted that the application specifically indicates on page 4 of the application that the Xac-Z-Ser-Gly-Ser-Gly formula represents the required heparin sulfate binding sequence. As the amended claims do not require the presence of this complete formula, and as this formula is indicated a required for the claimed function, the rejection is maintained on this basis.

8. **(Prior Rejections- Withdrawn)** Claim 3 was rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for fusion proteins comprising residues 20-41 of SEQ ID NO: 9 that bind to chondroitin sulfate in addition to heparan sulfate, does not reasonably provide enablement for any variant of the sequence that maintains chondroitin sulfate binding activity. The claim was also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for similar reasons to the rejection of claims 1-4, 15, and 16 above. These rejections are therefore withdrawn in favor of the general rejections of claims 1-4, 15, and 16 above.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application

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claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. **(New Rejection)** Claims 1, 3, 4, and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-21 of U.S. Patent No. 5,486,599. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent and the present claims read on overlapping subject matter. The present claims read on fusion proteins comprising a heparan sulfate binding regions corresponding to residues 20-41 of SEQ ID NO: 9 in which at least one amino acid may be conservatively substituted. However, the rejected claims provide for no minimum sequence homology. Nor do the claims indicate that only conservative substitutions may be made. The only structural requirement is that the SGSG heparan sulphate-binding region is maintained.

The patent provides the same teachings as the present application. The indicated patent claims read on a fusion protein comprising a portion of syndecan protein according to the formula of SEQ ID NO: 15 and a heterologous protein. A comparison of SEQ ID NO: 15 with residues 20-41 of SEQ ID NO: 9 shows that SEQ ID NO: 15 shares at least one conservative modification from the sequence of SEQ ID NO: 9. Thus, the syndecan portion of the fusion proteins in the patent overlap with the scope of the heparan sulphate binding regions in the

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presently claimed fusion proteins. Further, the patent specification, like the present specification, suggests the addition of such a syndecan sequence to a growth factor, and identifies GMCSF as a growth factor. See e.g., Figure 4, and columns 34-35. Thus, a fusion according to the patent claims wherein the heterologous protein is GMCSF represents an obvious variation of the claimed invention in the patent. In view of the overlapping scope of the patent and the present claims, the present claims are rejected for obviousness type double patenting.

11. **(New Rejection)** Claims 1-4, 15, and 16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, and 6 of U.S. Patent No. 5,486,599. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent and the present claims read on overlapping subject matter. The present claims have been described above. The claims of the patent provide substantially similar limitations to the present claims, except that the patent claims refer to residues 32-51 of SEQ ID NO: 6 instead of residues 20-41 of SEQ ID NO: 9. However, as in the present case, the patent claims provide no limitation with respect to the scope of the modifications that may be made to the heparan sulphate-binding domain other than that it must retain the heparan sulfate-binding domain (i.e., it must comprise a SGSG sequence). Not only does SEQ ID NO: 6 fall within the scope of the present claims, but residues 32-51 of SEQ ID NO: 9 is both disclosed as a useful alternative to residues 32-51 of SEQ ID NO: 6 (see e.g., columns 36-37) and falls within the scope of the patent claims. Thus, the present claims represent obvious embodiments of the patent claims.

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12. The above rejections are, in part, based on the specification of a previously issued patent, rather than the claims. In support of the use of this material, the examiner notes the following excerpt from MPEP section 804 II (B)(1):

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is based. This is true even where elements are drawn from the specification describing the claimed invention which are not elements in the claim itself.

Conclusion

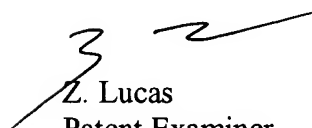
13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

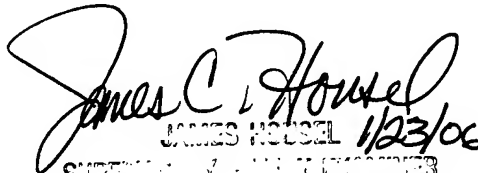
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
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